PROPOSED INTERNATIONAL COLOR CLASSIFICATION FRAMEWORK

for Binary Blood Typing and Visual Output Integration

Technical white paper - proposed framework for standards development, engineering validation, human-factors evaluation, and future international standardization consideration

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Status: Draft proposed framework - not an ISO standard, certification, or clinical-use authorization.

Executive Summary

This white paper defines a proposed five-color visual classification layer for blood-typing systems that translate serologic reactions into binary logic and then into a standardized visual output. The core concept preserves conventional ABO and Rh(D) terminology as the authoritative clinical interpretation while adding a machine-readable and human-readable output layer intended to improve rapid recognition, device interoperability, and consistent display behavior.

The proposed BINGO-inspired color family is: **Blue = A**, **Red = B**, **White = AB**, **Green = O**, and **Yellow = exception/referral state**. Yellow is deliberately defined here as an exception or special-review indication rather than a definitive 'golden blood' (Rh-null) diagnosis, because routine Anti-D testing alone cannot establish the Rh-null phenotype.

The recommended digital representation is a three-bit vector **[A,B,D]**, where each bit records the validated reaction state to Anti-A, Anti-B, and Anti-D respectively. This yields eight ordinary ABO/Rh(D) combinations. Color is an auxiliary communication layer; it must never be the sole carrier of clinically significant information.

Safety principle: any future clinical implementation requires analytical and clinical performance validation, risk management, usability engineering, quality-system controls, and applicable regulatory authorization. Color-blind accessibility and redundant text/symbol coding are mandatory design objectives.

1. Intended Purpose and Scope

The framework is intended to support development of an internationally reproducible visual-output convention for automated or semi-automated ABO/Rh(D) blood typing. It addresses the output and classification layer: reaction capture, binary encoding, visual mapping, exception handling, quality-control states, display specification, and validation. It does not redefine blood-group biology and does not replace established serologic methods, transfusion-service procedures, confirmatory testing, or local regulatory requirements.

2. Proposed System Architecture

Color is downstream of validated blood-group interpretation; it is not a substitute for the interpretation.

3. Canonical Binary Encoding

Recommended encoding: **A=1** when the Anti-A reaction is validated positive; **B=1** when Anti-B is validated positive; **D=1** when Anti-D is validated positive. A zero represents a validated negative reaction. Invalid, indeterminate, mixed-field, discrepant, or QC-failed reactions must not be forced into a 0/1 result; they require a separate status flag.

Vector [A,B,D]	ABO/Rh(D)	Primary color	Required redundant display
101	A positive	Blue	A+ / 101
100	A negative	Blue	A- / 100
011	B positive	Red	B+ / 011
010	B negative	Red	B- / 010
111	AB positive	White	AB+ / 111
110	AB negative	White	AB- / 110
001	O positive	Green	O+ / 001
000	O negative	Green	O- / 000

Compatibility note: the source drawing uses a two-part concept (ABO code plus an Rh(D) output). The three-bit [A,B,D] vector above is recommended as the canonical interoperable representation because it directly records the three validated reaction channels while preserving the original four ABO color assignments.

4. Five-Color Classification Specification

The following values are **provisional engineering targets** for prototype consistency, not validated international color coordinates. Final values should be established through device characterization, human-factors testing, accessibility testing, and manufacturing tolerances.

Color	Assigned meaning	Prototype sRGB / HEX	Display rule
Blue	ABO group A	0, 102, 204 / #0066CC	Always pair with A+ or A- and binary vector
Red	ABO group B	204, 0, 0 / #CC0000	Always pair with B+ or B- and binary vector
White	ABO group AB	245, 245, 245 / #F5F5F5	Use dark border/text; pair with AB+/AB-
Green	ABO group O	0, 128, 64 / #008040	Always pair with O+ or O- and binary vector
Yellow	Exception / referral / special review	255, 204, 0 / #FFCC00	Never use alone as a blood-group diagnosis

4.1 Objective Color Measurement

For emitted LED indicators, specification should ultimately include measured chromaticity (for example CIE x,y or u',v'), luminance range, spectral characteristics as appropriate, viewing angle, ambient-light limits, temperature dependence, aging tolerance, and device-to-device variation. For printed or reflective labels, color should be characterized under a defined illuminant/observer condition (for example D65/2-degree) using instrumental colorimetry. Prototype sRGB values are insufficient by themselves for an international standard.

4.2 Accessibility and Redundancy

No clinical state should be communicated by color alone. Each result should include at least two independent cues: conventional ABO/Rh(D) text and the binary vector, with optional symbols or shapes. This reduces risk for users with color-vision deficiency, poor display calibration, low ambient visibility, or cross-cultural color interpretation differences.

5. Yellow / 'Golden Blood' Safety Clarification

Rh-null ('golden blood') is a rare phenotype involving absence of Rh antigens and cannot be established merely from a negative Anti-D reaction. Therefore, this framework does not map routine D-negative results to yellow and does not permit a yellow indicator to assert Rh-null. Yellow is reserved for a configurable exception/referral state such as an unresolved discrepancy, rare-phenotype referral, extended-testing request, or other laboratory-defined special condition. A definitive rare-phenotype label would require appropriate extended serology and/or molecular confirmation under the responsible laboratory's procedures.

6. Result-State Model

State	Meaning	Recommended output behavior
VALID	All required reactions and QC criteria passed	Show ABO/Rh(D), [A,B,D], primary color
RETEST	Borderline or repeat criteria triggered	Suppress final color; show RETEST
INVALID	Assay or instrument validity failure	Suppress blood type; show INVALID
DISCREPANT	Forward/reverse or other interpretation conflict	Suppress final color; show discrepancy flag
SPECIAL REVIEW	Rare/exception pathway invoked	Yellow + explicit text; no unsupported diagnosis

7. Proposed Validation Program

Domain	Minimum evidence objective
Analytical performance	Agreement with reference ABO/Rh(D) methods; sensitivity to weak/mixed reactions; interference and carryover studies
Binary logic	Deterministic mapping, boundary handling, invalid-state protection, software verification and traceability
Color performance	Chromaticity/luminance tolerances, ambient-light robustness, aging, viewing angle, display-to-display reproducibility
Human factors	Recognition accuracy, time-to-interpretation, color-vision-deficiency testing, use-error analysis, training burden
Clinical workflow	Concordance in representative specimens and intended-use environments; discrepancy and repeat workflows
Quality control	Positive/negative controls, reagent lot controls, instrument self-checks, lockouts and audit trail
Cyber/data interoperability	Unambiguous machine-readable result schema, versioning, data integrity, timestamping and traceability

8. Alignment With Existing International Standards

The proposed color-classification framework is not itself an ISO standard. A future standards proposal should be designed to coexist with established requirements rather than imply certification. The following standards are relevant anchors for development and validation.

Standard	Relevance to proposed framework
ISO 14971:2019	Risk-management process for medical devices, including IVD devices; use to identify hazards such as wrong-result display, color
IEC 62366-1:2015	Usability engineering related to safety; relevant to color recognition, labeling, workflow, use errors, and redundant result presentati
ISO 18113-1:2022	General requirements and principles for information supplied by manufacturers of IVD medical devices.
ISO 18113-2:2022	Manufacturer information for IVD reagents, calibrators, and controls intended for professional use.
ISO 18113-3:2022	Manufacturer information for professional-use IVD instruments; relevant to reader/display instructions and result presentation.
ISO 15189:2022	Quality and competence requirements for medical laboratories; relevant to laboratory implementation and validation context.
ISO 23640:2011*	Stability evaluation for IVD reagents. ISO lists a replacement draft (ISO/DIS 23640) in development as of August 2026.

*Status should be rechecked at the time of any formal submission because standards are revised and superseded.

9. Suggested Standards-Development Pathway

1. Freeze the terminology. Define the five colors, [A,B,D] vector, status flags, intended use, and prohibited interpretations.

2. Create a design input specification. Establish colorimetric targets, luminance, tolerances, redundant text/symbol rules, data schema, and fail-safe behavior.

3. Perform bench verification. Verify logic mapping, display reproducibility, ambient-light performance, aging, and device-to-device consistency.

4. Conduct human-factors validation. Test trained and intended users, including color-vision-deficient participants, under realistic workflow conditions.

5. Conduct clinical/performance studies. Demonstrate agreement and safe handling of weak, discrepant, mixed-field, and invalid results.

6. Build the standards proposal package. Prepare scope, normative definitions, test methods, acceptance criteria, rationale, risk file, validation evidence, and interoperability examples.

7. Seek formal standards engagement. Engage the appropriate national standards body and relevant ISO/TC 212 pathway for IVD standardization consideration; do not market the framework as ISO-approved before formal adoption.

10. Proposed Normative-Style Requirements

• The system **shall** preserve conventional ABO and Rh(D) text in every final valid result.

• The system **shall** encode validated Anti-A, Anti-B, and Anti-D reaction states using a documented binary representation or an equivalent unambiguous machine-readable representation.

• The system **shall not** convert invalid, indeterminate, discrepant, or QC-failed reactions into an ordinary ABO/Rh(D) color result.

• The system **shall not** use color as the sole means of communicating a blood-group result.

• The color output **shall** meet specified chromaticity/luminance tolerances over the defined operating environment and service life.

• Yellow **shall** indicate an exception/referral state unless a separately validated application defines another meaning; it shall not by itself indicate Rh-null.

• The system **shall** provide traceability from raw reaction state to binary code, interpreted blood group, displayed color, and transmitted digital result.

11. Interoperability Record Example

```
Result: A positive
Vector: [1,0,1]
PrimaryColor: BLUE
Status: VALID
AntiA: POSITIVE
AntiB: NEGATIVE
AntiD: POSITIVE
DisplayText: A+
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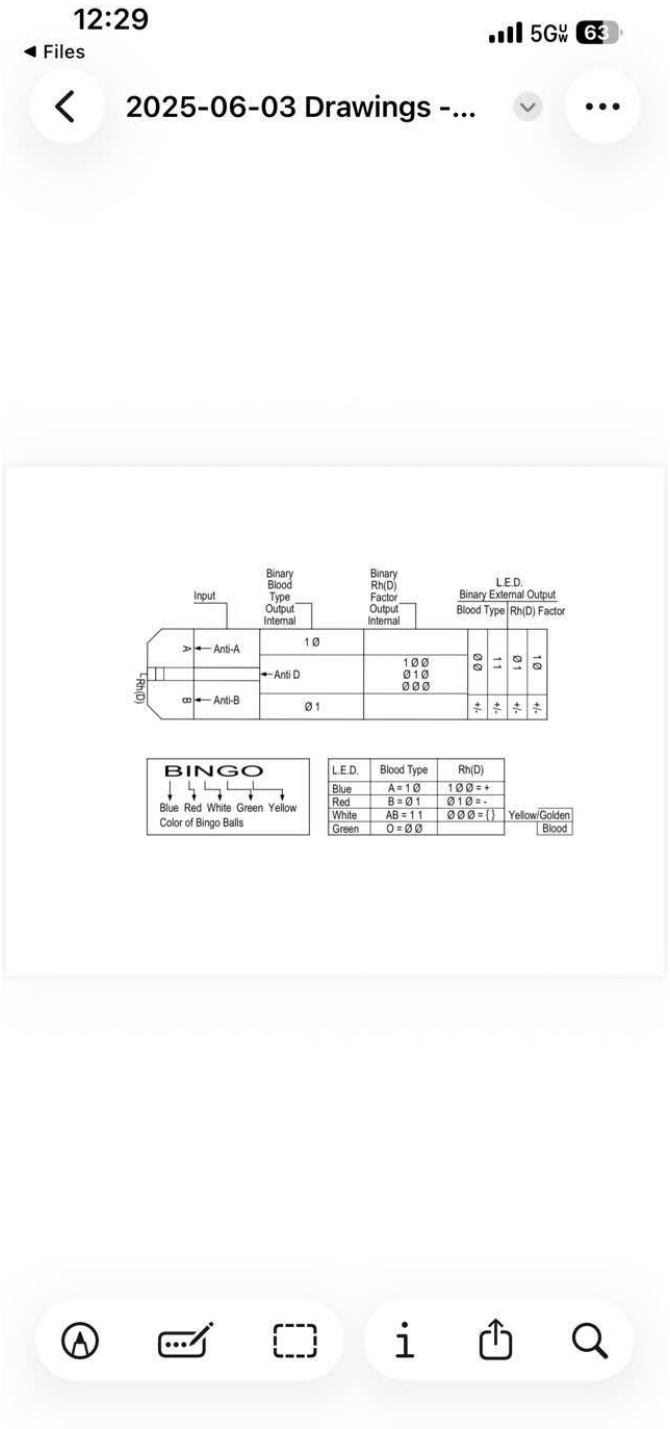
12. Source Concept Drawing

The following image is the source concept supplied for this white paper. It documents the original BINGO color association and binary-output concept. The standardized recommendations in this paper intentionally clarify the encoding and exception-state behavior while preserving the core concept.



13. References and Status Notes

• ISO 14971:2019, Medical devices - Application of risk management to medical devices. ISO lists the 2019 edition as current and confirmed in 2025.

• IEC 62366-1:2015, Medical devices - Part 1: Application of usability engineering to medical devices.

• ISO 18113-1:2022, In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1.

• ISO 18113-2:2022, In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2.

• ISO 18113-3:2022, In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 3.

• ISO 15189:2022, Medical laboratories - Requirements for quality and competence.

• ISO 23640:2011, In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents; ISO/DIS 23640 is listed by ISO as a replacement draft in development as of August 2026.

Document-control note. This is a proposed technical framework prepared for concept development and standards planning. It is not a published ISO standard, not evidence of ISO qualification or certification, and not authorization for clinical use. Standards status and regulatory requirements should be verified at the time of formal development, submission, or commercialization.